STATE OF TENNESSEE
DEPARTMENT OF MENTAL HEALTH AND SUBSTANCE ABUSE SERVICES
601 MAINSTREAM DRIVE
NASHVILLE, TENNESSEE 37243-0675

BILL HASLAM
GOVERNOR

E. DOUGLAS VARNEY
COMMISSIONER

MEMORANDUM

TO: Melanie Hill, Executive Director
Health Services and Development Agency

FROM: Sandra Braber-Grove, Director, Office of Contracts and Privacy / Assistant General Counsel
TDMHSAS Division of General Counsel

DATE: June 11, 2013

RE: Review and Analysis of Certificate of Need Application
Tri-Cities Holdings LLC d/b/a Trex Treatment Center - CN1303-005

Pursuant to and in accordance with Tennessee Code Annotated (TCA) § 68-11-1608 and Rules of the Health Services and Development Agency including the Criteria and Standards for Certificate of Need (2000 Edition, Tennessee's Health Guidelines for Growth, prepared by the Health Planning Commission) [hereinafter Guidelines for Growth], staff of the Tennessee Department of Mental Health and Substance Abuse Services (TDMHSAS), the licensing agency, have reviewed and analyzed the above-referenced application for a Certificate of Need.

Attached is the TDMHSAS report. At a minimum and as noted in TCA § 68-11-1608, the report provides:

(1) Verification of application-submitted information;

(2) Documentation or source for data;

(3) A review of the applicant's participation or non-participation in Tennessee's Medicaid program, TennCare or its successor;

(4) Analyses of the impact of a proposed project on the utilization of existing providers and the financial consequences to existing providers from any loss of utilization that would result from the proposed project;

(5) Specific determinations as to whether a proposed project is consistent with the state health plan; and

(6) Further studies and inquiries necessary to evaluate the application pursuant to the rules of the agency.

If there are any questions, please contact me at (615) 532-6520.

cc: E. Douglas Varney, Commissioner, TDMHSAS
Marie Williams, Deputy Commissioner, TDMHSAS
Dr. Jason Carter, Pharm. D., TDMHSAS, Chief Pharmacist and State Opioid Treatment Authority (SOTA)
Cynthia Clark Tyler, Director of Licensure, TDMHSAS

REVIEW AND ANALYSIS
CERTIFICATE OF NEED APPLICATION
CN1303-005

Pursuant to and in accordance with Tennessee Code Annotated (TCA) § 68-11-1608 and Rules of the Health Services and Development Agency including the Criteria and Standards for Certificate of Need (2000 Edition, Tennessee's Health Guidelines for Growth, prepared by the Health Planning Commission) [hereinafter Guidelines for Growth], staff of the Tennessee Department of Mental Health and Substance Abuse Services (TDMHSAS), the licensing agency, have reviewed and analyzed the application for a Certificate of Need submitted by Mr. Steven W. Kester on behalf of Tri-Cities Holdings, LLC for the establishment of a new "outpatient opiate treatment program (OTP)" (also referred to as a "Non-Residential Substitution-Based Treatment Center for Opiate Addiction"; "Opioid Treatment Program" (OTP); or "methadone clinic"). The Applicant proposes to establish the facility at 4 Wesley Court in Johnson City, Washington County, Tennessee.

The report has three (3) parts:

A. Summary of Project
B. Conclusions
C. Analysis - in three (3) parts:

Need	**Economic Feasibility**	**Contribution to the Orderly Development of Health Care**
Evaluated by the following general factors: a. Relationship to any existing applicable plans; b. Population to be served; c. Existing or Certified Services or Institutions; d. Reasonableness of the service area; e. Special needs of the service area population (particularly women, racial and ethnic minorities, and low-income groups); f. Comparison of utilization/ occupancy trends and services offered by other area providers; g. Extent to which Medicare, Medicaid, and medically indigent patients will be served; and h. Additional factors specified in the Tennessee's Health Guidelines for Growth publication for this type of facility.	Evaluated by the following general factors: a. Whether adequate funds are available to complete the project; b. Reasonableness of costs; c. Anticipated revenue and the impact on existing patient charges; d. Participation in state/federal revenue programs; e. Alternatives considered; f. Availability of less costly or more effective alternative methods; and g. Additional factors specified in the Tennessee's Health Guidelines for Growth publication.	Evaluated by the following general factors: a. Relationship to the existing health care system (i.e., transfer agreements, contractual agreements for health services, and affiliation of the project with health professional schools); b. Positive or negative effects attributed to duplication or competition; c. Availability and accessibility of human resources required; d. Quality of the project in relation to applicable governmental or professional standards; and e. Additional factors specified in the Tennessee's Health Guidelines for Growth publication.

A. SUMMARY OF PROJECT

Mr. Steven W. Kester (identified as the Managing Member or Manager) has submitted, on behalf of Tri-Cities Holdings, LLC d/b/a/ Trex Treatment Center (Applicant), an application for a Certificate of Need seeking the establishment of a new "outpatient opiate treatment program (OTP)" to be located at 4 Wesley Court in Johnson City, Washington County, Tennessee. An "outpatient opiate treatment program" is also referred to as a "Non-Residential Substitution-Based Treatment Center for Opiate Addiction"; "Opioid Treatment Program" (OTP); or "methadone clinic"). On the Applicant Profile, for Type of Institution (Item 7.), the Applicant selected "Non-Residential Methadone Facility" (Item 7.N.). The purpose of review is "New Institution" (Item 8.A.).

The Applicant reports that its Manager is the co-founder and part-owner of nine (9) treatment programs, but information provided in the application [Supplemental #1, Page 4] names only seven (7): two (2) in the Asheville area (Crossroads Treatment Centers of Weaverville, NC and Asheville); three (3) more in Asheville (Western Carolina, CRC, and Mountain Area Recovery Center); and two (2) in Boone, NC (Stepping Stone and McLeod).

If the Certificate of Need application is approved and all other requirements are met, the facility would be licensed by the Tennessee Department of Mental Health and Substance Abuse Services (TDMHSAS). Information provided in the application indicates that it is anticipated that the facility will use buprenorphine, methadone, and abstinence-based treatment for "those suffering from opiate addiction." [Supplemental #1, Page 4] Applicant also reports that the facility will offer individual counseling services and group therapy to "help break the cycle of addiction and provide patients the life skills and resources to serve as productive members of their communities, families and employers." [Supplemental #1, Page 4] The Applicant reports that the commitment will be "to give patients their independence back as soon as medically, morally and ethically possible." [Supplemental #1, Page 4]

The Applicant reports that the proposed service area is the nine (9) most northeastern counties of Tennessee: Sullivan, Washington, Greene, Hamblen, Carter, Hawkins, Cocke, Unicoi, and Johnson, which reportedly covers 100% of the population of Tennessee's Methadone Service Area (MSA) #1, 97% of MSA #2, and 70% of MSA #3. The Applicant further reports that six hundred (600) patients from Northeast Tennessee travel to the Asheville facilities for services, and an admissions counselor at the Knoxville facility (owned by the Behavioral Health Group) indicated, in a phone call placed by the Applicant's Manager on February 25, 2013, that "nearly four hundred (400)" patients from Northeast Tennessee are served in their facility. [Supplemental #1, Page 4]

The Applicant reports that there is no major medical equipment involved in the project other than the dispensing devices used to correctly administer medication doses. The Applicant reports that the proposed building on the proposed site (at 4 Wesley Court) expected to be used for the facility requires no structural modifications, but will be

renovated as follows: the lobby will be re-purposed as a waiting room; large rooms will be partitioned to create offices for counselors, doctors, and the Executive Director; other large rooms will be partitioned and have plumbing added for use as examination and lab rooms; dosing rooms and associated dosing windows will be constructed; a room for the pharmacy and associated medicine vault will be constructed; a check-in booth will be constructed; and electrical, cabling, video, and telephony will be added in/for all rooms. [Supplemental #1, Page 6] The Applicant also reports that the total estimated project cost is $670,000.00 which includes $320,000.00 for facility costs [lease at an average of $5,333.00 per month]; $160,000.00 for preparation of site costs; $80,000.00 for "operating loss carry" which was explained as the amount that needs to be financed during the time between when the facility opens until it becomes cashflow positive; and $30,000.00 for legal, administrative, and consultant fees which the Applicant reported includes accreditation by the Commission on Accreditation of Rehabilitation Facilities (CARF). If the application is approved, the anticipated date construction (renovation; approved for occupancy) will be 100% complete is November 2013 with the issuance of a license occurring in January 2014 and the initiation of services occurring in February 2014.

B. CONCLUSIONS

As previously stated, if the application is approved and all other requirements are met, the facility would be licensed by the TDMHSAS. TDMHSAS staff have reviewed and analyzed the application and cannot support approval of the application because the majority of the Criteria and Standards for the type of facility being proposed in the application have not been met as explained below:

1. A note about specific criteria for a non-residential methadone facility. In addition to the other general criteria, the application for a Certificate of Need for a non-residential methadone facility should also address these and other specific criteria as listed in the Guidelines for Growth: 1) A non-residential methadone facility should provide adequate medical, counseling, vocational, educational, mental health assessment, and social services to patients enrolled in the program with the goal of the individual becoming free of opioid dependency; 2) Need should be based on information prepared by the Applicant which acknowledges the importance of considering the demand for services along with need as well as addressing and analyzing service problems; 3) The need assessment should also cover the proposed service area and include the utilization of existing service providers, scope of services provided, patient origin, and patient mix; 4) The Applicant should show that the geographic service area is reasonable and based on an optimal balance between population density and service proximity and show that the project is sensitive and responsive to the special needs of the service area in terms of accessibility to consumers, particularly women, racial and ethnic minorities, and low-income groups; and 5) The Applicant should show the project's relationship to policy as formulated in local and national plans, including need methodologies.

2. Need has not been clearly established as described in further detail in Section C.1. Overall, need has not been clearly established. The Applicant takes national projections and applies them to Tennessee and specifically Upper Northeast, Tennessee resulting in a misrepresentation of need. As mentioned in Section B.1., in addition to the general factors noted on Page 2 of this report, there are additional specific criteria for the type of facility proposed in the application under review. Many of the conclusions and inferences drawn by the Applicant from cited references are not scientifically based and national studies and statistics are mis-applied to the Upper Northeast, Tennessee area. The Applicant reports that the distance required to travel to treatment is a barrier to treatment and provides some statistics on distances from counties within the proposed service area to one of the existing clinics in Asheville, NC as well as the Knoxville, TN clinic. It is also reported that six hundred (600) patients from Northeast Tennessee travel to the Asheville, NC facilities for services, and an admissions counselor at the Knoxville, TN facility (owned by the Behavioral Health Group) indicated, in a phone call placed by the Applicant's Manager on February 25, 2013, that "nearly four hundred (400)" patients from Northeast Tennessee are served in their facility. [Supplemental #1, Page 4] The specifics of where in "Northeast Tennessee" these patients are located and, therefore, the distance they travel to Asheville, NC or Knoxville, TN is not provided by the Applicant, except that it is noted that the Knoxville, TN clinic is 104 miles from the proposed project location. Other data was submitted showing travel distances from Johnson City, Kingsport, and Bristol to Asheville, NC and Knoxville, TN; but the 1,000 patients reported to be receiving treatment in either the Asheville, NC or Knoxville, TN clinic have only been identified as being from "Northeast Tennessee", not these cities in particular, so it is not clear if the proposed project would improve driving distances for the reported existing patients. When discussing need in terms of where prescription pain medication abuse is the highest, the Applicant reports that the abuse of prescription pain medication is an epidemic in the United States and that the rate of abuse is higher in the proposed service area; however, as discussed in more detail in Section C.1., the study cited for this statement includes "Overall Conclusions" beginning on Page 226 of the study that report that "admission rates for the primary abuse of other opiates and synthetics [including hydrocodone, oxycodone, and any other drug with morphine-like effects except methadone] are higher in Appalachia than in the rest of the nation" [and] "in many ways, access to treatment is better in Appalachia when compared to the rest of the nation." The Applicant reports that there are "no existing SAMHSA-designated methadone maintenance treatment programs in [the] proposed service area"; therefore, there is a need. [Supplemental #1, Page 4] While it is true that there are no methadone clinics in the proposed service area, it is not true that there isn't access to medication assisted therapy and other forms of treatment in the proposed service area for those suffering from opioid addiction, as demonstrated in the list of providers submitted with the application. [Supplemental #1, Pages 99-103]

3. Economic Feasibility has possibly been established as described in further detail in Section C.2. The overall cost of the proposed project appears to be reasonable and, if the application is approved and all other requirements are met, the project should be able to be completed in a timely manner. The Applicant reports that the project will be funded personally by Mr. Steven W. Kester, identified as the "Managing Member of Applicant". It is reported that the monies are in reserve and have been committed to more than cover the project costs and start-up operating loss(es). In a March 15, 2013 letter from the Health Services and Development Agency (HSDA) to Applicant, Applicant is requested to submit a letter from a banking institution, Certified Public Accountant, etc. that demonstrates financial resources and/or reserves to implement the proposed project. In Supplemental #2 information, there is a facsimile from the Maxim Group indicating brokerage account balances of Mr. Steven W. Kester as of March 27, 2013. In a later letter from the HSDA to Applicant, the facsimile is noted, but there is another request for a letter from a banking institution, Certified Public Accountant, etc. that demonstrates financial resources and/or reserves to implement the proposed project. Staff of the TDMHSAS reviewing the application cannot find the requested documentation, but do take note of the statements in the application that the Applicant's Manager has sufficient resources in a brokerage account under his control for purposes of financially securing this project and that "all funds required to open and outfit this facility, and cover the operating loss during the first year, plus contingency, are secured." [Supplemental #1, Page 40] A review of the proposed charges for methadone at the facility causes concern to TDMHSAS licensure staff as discussed in Section C.2.

4. The project does not contribute to the orderly development of healthcare as described in further detail in Section C.3. The application under review is for a new facility. The Applicant, Tri-Cities Holdings, LLC d/b/a Trex Treatment Center, was organized pursuant to the Georgia Limited Liability Company Act on January 15, 2013 and was established to "engage solely for the formation of an opiate treatment program in the 'Tri-Cities' region of Tennessee and Virginia ...." [Supplemental #1, Page 75] Therefore, the Applicant has no prior experience in the operation of this type of facility or program other than the leadership and experience of its Manager who has "successfully opened nine (9) such facilities in four (4) states in five (5) years." [Supplemental #1, Page 5] When discussing transfer agreements, contractual agreements for health services, and affiliation of the project with health professional schools, since this is a new project, there are no existing agreements and affiliations, but the Applicant reports that it intends to have transfer relationships with all emergency hospitals in the Tri-Cities and surrounding area. Applicant also reports significant experience developing internships and other partnerships with local universities and professional societies, and looks forward to establishing these in the proposed service area. [Supplemental #1, Pages 42 and 44] As of the writing of this report, there are no letters of support from any of these entities in the proposed service area. When discussing staffing and the availability and accessibility of human resources required for the project, Applicant reports that it

recognizes the challenge of hiring and keeping the right staff and reports that all personnel will satisfy the TDMHSAS licensure rules, however, the staffing chart provided on Supplemental #1, Page 43 does not contain enough information to determine, at this time, if the staffing requirements will be met. For the criteria requesting documentation of deficiencies, if any, for existing licensed providers, and when the Applicant was requested to provide health survey results for the centers in North Carolina for which the Applicant's Manager claims "co-founder" and "part-owner" status, the response was that Applicant is a "shareholder of the company that operates these centers, but is not an officer or member of management ... [so] has no access to these records." [Supplemental #1, Page 45] Applicant verifies that it has reviewed and understands the licensure requirements of the Department of Health, the Department of Mental Health and Substance Abuse Services, and/or any applicable Medicare requirements. In information provided in Supplemental #2 [Page 4 of a Mach 27, 2013 letter], Applicant also reports that TDMHSAS staff explained the licensing and Central Registry procedures for this type of program, however, the response to whether the Applicant will provide the HSDA and/or the reviewing agency information concerning the number of patients treated, the number and type of procedures performed, and other data as required, the Applicant responded "Yes, subject to Federal HIPAA regulation." [Supplemental #1, Page 45] It is unclear whether Applicant is fully aware of and understands the complexity of all federal, Tennessee, and local laws, regulations, rules, and ordinances governing the establishment and operation of this type of facility and program. When asked about alternatives, the Applicant reported that more than fifty (50) locations in the Tri-Cities area were reviewed before selecting the proposed site of 4 Wesley Court. Further, the Applicant reported that the proposed site best meets the zoning requirements and was chosen because it is located in the biggest city of the proposed service area; is close to the maximum number of anticipated patients; has ready highway access to all points within the proposed service area; and requires only modifications to an existing structure, no new construction. [Supplemental #1, Page 41] The Applicant reports that it has "balanced cost control with providing patients quality care and a healing environment." [Supplemental #1, Page 41] In the March 15, 2013 letter from HSDA to Applicant, the Applicant was requested to provide a current letter from the City of Johnson City that the proposed site meets zoning requirements. Staff of the TDMHSAS reviewing the application cannot find the requested documentation, but do take note of statements in the application that the Applicant has requested zoning variances to accommodate this project. See Section C.3. for further discussion about zoning.

C. ANALYSIS

1. Need

Tri-Cities Holdings, LLC d/b/a/ Trex Treatment Center (Applicant) is seeking the establishment of a new "outpatient opiate treatment program (OTP)" to be located at 4

Wesley Court in Johnson City, Washington County, Tennessee. An "outpatient opiate treatment program" is also referred to as a "Non-Residential Substitution-Based Treatment Center for Opiate Addiction"; "Opioid Treatment Program" (OTP); or "methadone clinic").

Overall, need has not been clearly established. The Applicant takes national projections and applies them to Tennessee and specifically Upper Northeast, Tennessee resulting in a misrepresentation of need. Many of the conclusions and inferences drawn by the Applicant from cited references are not scientifically based and national studies and statistics are mis-applied to the Upper Northeast, Tennessee area.

When asked to provide the estimated number of persons, in the described area, addicted to heroin or other opioid drugs and an explanation of the basis for the estimate, the Applicant reports that there are approximately between 12,000 and 24,000 adults who are addicted to opiates in the proposed service area. The Applicant derived these from the following: the Substance Abuse and Mental Health Services Administration (SAMHSA) reports that "heroin use was 0.3% in 2011 and prescription pain medication abuse was 1.7% [therefore] combined, this would yield 12,000 opiate abusers or opiate dependents from the proposed service area." [Supplemental #1, Page 19] Further, the Applicant reports that the Tennessee Safety Subcabinet Working Group report [*Prescription Drug Abuse in Tennessee*] indicates that "almost 250,000 Tennesseans older than 12 reported abusing prescription opioids in 2009; Tennessee's population was approximately 6.3 million in 2009, yielding an incidence rate of 3.9%; this alone would yield approximately 23,800 opiate abusers or opiate dependents from the proposed service area." [Supplemental #1, Page 14] It is not clear how the Applicant arrived at its numbers. Further, the Applicant reports that an estimated number of 950 and 1,500 individuals from the proposed service area are in methadone treatment, relying on data from the methadone clinics in the Asheville, NC area, Knoxville, TN, and Boone, NC. [Supplemental #1, Pages 19-20] Due to a change in federal regulations, current Tennessee Methadone Central Registry data is not available. However, Applicant did provide calendar year 2008 data from the Tennessee Methadone Central Registry. [Supplemental #1, Pages 110B-110G] The Applicant incorrectly calculated that this data shows 8,889 Tennessee individuals receiving services at Tennessee methadone clinics. The Applicant did not deduct the number of individuals reported with a "county of residence" of 'unknown', nor did the Applicant deduct the number of individuals reported with a "county of residence" of 'out of state'. Using Applicant's figures of 8,889 and a state population at the time (2008) of 6,156,719, Applicant reports that there would be 866 patients in the proposed service area. [Supplemental #1, Page 19] Looking at the calendar year 2008 data and adding up the number of individuals with a "county of residence" of each of the nine (9) counties in the proposed service area, there are a total of 150 individuals from all nine (9) counties of the proposed service area, combined, reported to be receiving methadone treatment at the Knoxville, TN clinics. As mentioned, current data from the Tennessee Methadone Central Registry is not available, but it is not believed that there has been what amounts to a 2.5 times increase in the number of people from the counties in the proposed service area receiving services from a methadone clinic, which

is what would be needed to arrive at the Applicant's reported number of "nearly 400" patients receiving treatment at the Knoxville, TN clinic.

Need is also evaluated by the factors of special needs of the service area population, particularly women, racial and ethnic minorities, and low-income groups as well as the extent to which Medicare, Medicaid, and medically indigent patients will be served. Participation in Medicare and Medicaid is discussed in Section C.3. The Applicant states that a CDC report "clearly shows that opioid abuse and overdose cuts across genders, age groups, race, metropolitan status and economics [and] shows that Tennessee is among the 12 states with the highest per-capita overdose rates in the nation." [Supplemental #2, Page 22] A review of the cited reference [http://www.fda.gov/downloads/Drugs/NewsEvents/UCM300859.pdf] cannot confirm the Applicant's statements; the author of the cited reference states that "the findings and conclusions in this report are those of the author and do not represent the official position of the Centers for Disease Control and Prevention." Furthermore, states that are specifically covered in the presentation include Ohio, Utah, North Carolina, West Virginia, and New Mexico, not Tennessee.

The Applicant reports that the proposed service area is the nine (9) most northeastern counties of Tennessee: Sullivan, Washington, Greene, Hamblen, Carter, Hawkins, Cocke, Unicoi, and Johnson, which reportedly covers 100% of the population of Tennessee's Methadone Service Area (MSA) #1, 97% of MSA #2, and 70% of MSA #3. Applicant further reports that the MSAs were specifically addressed to balance population with proximity to care and notes that "[b]asically, where the State said there should be three facilities in 2002, there are none today, and the need has become materially more pronounced since that time." The Applicant does not cite a reference in support of this particular statement. [Supplemental #2, Page 22] A map of the MSAs was included with the application [Attachment C.3., Supplemental #1, Page 119], and while there are some pages that identify which counties are included in which MSA [Supplemental #1, Pages 120-121], there is nothing else to use to verify the Applicant's statement regarding the number of facilities expected to be located in each MSA.

Additional information provided in Supplemental #2 gives more detail about MSAs. It is noted that Tennessee Public Chapter 363 of the Acts of the 2001 General Assembly created Methadone Service Areas (MSAs) on the assumption that the closer one lives to a treatment program, the greater likelihood of participation. It is noted that the rate of participation is nearly twice as high for those living in or near a county that houses a methadone program (59.0/100,000) than the rate for those that live sixty (60) miles or more from a program (32.2/100,000). [Supplemental #2, Page 3 of the March 27, 2013 letter] Noted in the Tennessee Department of Health's report prepared as a response to Public Chapter 363 of the Acts of the 2001 General Assembly [http://health.state.tn.us/Downloads/g6022004.pdf], the State of Tennessee had a proposal to designate twenty-three (23) MSAs within the state to assure that all Tennesseans who wished to participate in a methadone maintenance treatment (MMT) program would have reasonable access to a program. An MSA, patterned in concept after the use of Rational Service Areas by the Department of Health in helping identify underserved health resource shortage areas in the state, is described as a "county or

constellation of contiguous counties in the state that comprise a sufficient general population making it likely that a minimum number of opiate dependent persons reside in the MSA who wish treatment and could support a program. This minimum population foundation was balanced with the need to establish geographic boundaries such that patients living within the MSA would reside within less than an hour drive one-way to a treatment program if the program were established in the heart of the MSA." [Page 8 of the report/response] The Applicant reports that it is estimated that 90% of the proposed service area's population is within sixty (60) miles of the proposed project location. [Supplemental #2, Page 3 of the March 27, 2013 letter] However, since the 1,000 patients reported by Applicant to be receiving treatment in either the Asheville, NC or Knoxville, TN clinic have only been identified as being from "Northeast Tennessee", it is not clear that Applicant's statements and conclusions support a need for the proposed project.

One of the other facts noted in the Department of Health's report/response is that businesses that establish programs require a general population of at least 100,000 persons from which to draw potential clients, generating 67 clients on average. [Page 6 of the report/response] The Applicant reports that six hundred (600) patients from Northeast Tennessee travel to the Asheville, NC facilities for services, and an admissions counselor at the Knoxville, TN facility (owned by the Behavioral Health Group) indicated, in a phone call placed by the Applicant's Manager on February 25, 2013, that "nearly four hundred (400)" patients from Northeast Tennessee are served in their facility. [Supplemental #1, Page 4] The specifics of where in "Northeast Tennessee" these patients are located have not been provided.

In other information provided by the Applicant describing the relationship of the proposed site to public transportation routes and general accessibility of the proposed site to potential patients, the Applicant reports that the proposed site is less than a quarter of a mile to transit stops on Johnson City's Transit System Blue Route and that the proposed location is less than one mile to I-26; a 20-minute drive from Kingsport, and a 22 mile drive from Bristol. The Applicant submitted a chart that shows it is 45 miles from Johnson City, TN to Weaverville, NC; 104 miles from Johnson City, TN to Knoxville, TN; and would be 0 miles from Johnson City to the proposed project location representing a "major improvement of the driving distances patients currently go for treatment". [Supplemental #1, Page 14] Similar data was submitted for patients living in Kingsport and Bristol; however, the 1,000 patients reported to be receiving treatment in either the Asheville, NC or Knoxville, TN clinic have only been identified as being from "Northeast Tennessee", not these particular cities. Elsewhere in the application, when discussing need in terms of barriers to treatment, particularly the distance to treatment, the Applicant reports that "of the barriers to access to healthcare, geographic distance is [at] the top of the list, even higher than access to healthcare insurance." [Supplement #1, Page 5] The TDMHSAS staff reviewing the application cannot verify this statement due to the cited reference being incomplete. The Applicant points out that a Johnson City, TN patient travels 200 miles round trip to Knoxville, TN and consumes approximately $30.00 in gas and over three (3) hours of drive time, which is a hardship for patients, especially new patients who need to receive treatment seven (7) days per week. The Applicant further reports that "for every patient that makes the

commute, several are most likely foregoing treatment because they can't afford the time, money or energy." [Supplement #1, Page 5] It is interesting to note that the calendar year 2008 Tennessee Methadone Central Registry data shows only six (6) patients with a "county of residence" of 'Washington' receiving services at the Knoxville, TN clinics. The Applicant has not specifically identified any patients as being "Johnson City patients", but has only identified the 1,000 patients reported to be receiving treatment in either the Asheville, NC or Knoxville, TN clinic as being from "Northeast Tennessee"; therefore, it is not clear that Applicant's statement and conclusions support a need for the proposed project.

When discussing need in terms of where prescription pain medication abuse is the highest, the Applicant reports that the abuse of prescription pain medication is an epidemic in the United States and that the rate of abuse is higher in the proposed service area. However, the study cited by the Applicant for this statement [http://www.kentucky.com/static/pdfs/ARCreport.pdf] is from a May 2008 report by members of the National Opinion Research Center (NORC) at the University of Chicago and two members of East Tennessee State University presented to the Appalachian Regional Commission and is an analysis of disparities in mental health status and substance abuse prevalence, as well as access to treatment services in the entire 410 county Appalachian region comprising all or parts of thirteen (13) states, specifically all of West Virginia and parts of these twelve (12) states: Alabama, Georgia, Kentucky, Maryland, Mississippi, New York, North Carolina, Ohio, Pennsylvania, South Carolina, Tennessee, and Virginia. As noted in the study, the Appalachian region is home to more than 23 million people, extending from southern New York to northeast Mississippi and covers over 200,000 square miles of 410 counties in 13 states. The study does not specifically mention how many methadone clinics are in the Appalachian region, however, there are tables in the study that show that in 2005 there were a total of 891 substance abuse treatment facilities in the region with 16.59% of them providing Naltrexone; 8.24% of them providing methadone; 8.15% of them providing buprenorphine-Suboxone; and 5.10% of them providing Buprenorphine-Subutex (Pages 157-160). The study does not contain specifics on the locations of any of these facilities, so it is not clear that the results of this study can be appropriately applied to the proposed service area. It is interesting to note that in the "Overall Conclusions" statements of this study, beginning on Page 226, it is mentioned that "admission rates for the primary abuse of other opiates and synthetics [including hydrocodone, oxycodone, and any other drug with morphine-like effects except methadone] are higher in Appalachia than in the rest of the nation" [and] "in many ways, access to treatment is better in Appalachia when compared to the rest of the nation."

Last, but not least, when discussing the relationship of the proposed project to existing treatment in the proposed service area, the Applicant reports that there are "no existing SAMHSA-designated methadone maintenance treatment programs in [the] proposed service area"; therefore, there is a need. [Supplemental #1, Page 4] As stated previously, the Applicant takes national projections and applies them to Tennessee and specifically Upper Northeast, Tennessee resulting in a misrepresentation of need. Furthermore, many of the conclusions and inferences drawn by the Applicant from

cited references are not scientifically based and national studies and statistics are mis-applied to the Upper Northeast, Tennessee area. While it is true that there are no methadone clinics in the proposed service area, it is not true that there isn't access to medication assisted therapy and other forms of treatment in the proposed service area for those suffering from opioid addiction, as demonstrated in the list of providers submitted with the application. [Supplemental #1, Pages 99-103]

2. Economic Feasibility

A review of the information supplied by the Applicant shows that there should be sufficient funds available for this project. The Applicant reports that the project will be funded personally by Mr. Steven W. Kester, identified as the "Managing Member of Applicant". It is reported that the monies are in reserve and have been committed to more than cover the project costs and start-up operating loss(es). In a March 15, 2013 letter from the Health Services and Development Agency (HSDA) to Applicant, Applicant is requested to submit a letter from a banking institution, Certified Public Accountant, etc. that demonstrates financial resources and/or reserves to implement the proposed project. In Supplemental #2 information, there is a facsimile from the Maxim Group indicating brokerage account balances of Mr. Steven W. Kester as of March 27, 2013. In a later letter from the HSDA to Applicant, the facsimile is noted, but there is another request for a letter from a banking institution, Certified Public Accountant, etc. that demonstrates financial resources and/or reserves to implement the proposed project. Staff of the TDMHSAS reviewing the application cannot find the requested documentation, but do take note of the statements in the application that the Applicant's Manager has sufficient resources in a brokerage account under his control for purposes of financially securing this project and that "all funds required to open and outfit this facility, and cover the operating loss during the first year, plus contingency, are secured." [Supplemental #1, Page 40]

This application under review is for the establishment of a new facility to be operated as a non-residential methadone facility [Item 7.N. in the Applicant Profile] Such a facility is also referred to as an "outpatient opiate treatment program"; a "Non-Residential Substitution-Based Treatment Center for Opiate Addiction"; "Opioid Treatment Program" (OTP); or "methadone clinic". The Applicant, Tri-Cities Holdings, LLC d/b/a Trex Treatment Center, was organized pursuant to the Georgia Limited Liability Company Act on January 15, 2013 and was established to "engage solely for the formation of an opiate treatment program in the 'Tri-Cities' region of Tennessee and Virginia ...." [Supplemental #1, Page 75] Therefore, the Applicant has no prior experience in the operation of this type of program other than the leadership and experience of its Manager who has "successfully opened nine (9) such facilities in four (4) states in five (5) years." [Supplemental #1, Page 5] Information provided in the application [Supplemental #1, Page 4] names seven (7) facilities: two (2) in the Asheville area (Crossroads Treatment Centers of Weaverville, NC and Asheville); three (3) more in Asheville (Western Carolina, CRC, and Mountain Area Recovery Center); and two (2) in Boone, NC (Stepping Stone and McLeod).

The Applicant reports that the total estimated project cost is $670,000.00 which includes $320,000.00 for facility costs [lease at an average of $5,333.00 per month]; $160,000.00 for preparation of site costs; $80,000.00 for "operating loss carry" which was explained as the amount that needs to be financed during the time between when the facility opens until it becomes cashflow positive; and $30,000.00 for legal, administrative, and consultant fees which the Applicant reported includes accreditation by the Commission on Accreditation of Rehabilitation Facilities (CARF). Applicant reports that the costs were developed with the Applicant's experience of having opened nine (9) such facilities in four (4) states and are "standard work elements" such as wall construction and moving walls; adding electrical, phones, cable and security; reconfiguring heating and air conditioning systems; adding workrooms unique to this type of facility (dosing windows, pharmacy, payment area, check-in area); outfitting the offices with desks, computers, and phones; and installing patient and accounting software systems unique to this type of facility. [Supplemental #1, Page 33] When asked to provide data for the Historical Data Chart for Net Operating Revenue, Net Operating Income (Loss), and other such information, for the last three (3) years for a center in Asheville, NC for which Applicant claims ownership, Applicant responded that as a shareholder of the company, not an officer or member of management, there is no access to this information. [Supplemental #1, Page 34]

The Applicant reports that there is no major medical equipment involved in the project other than the dispensing devices used to correctly administer medication doses. The Applicant reports that the proposed building on the proposed site (at 4 Wesley Court) expected to be used for the facility requires no structural modifications, but will be renovated as follows: the lobby will be re-purposed as a waiting room; large rooms will be partitioned to create offices for counselors, doctors, and the Executive Director; other large rooms will be partitioned and have plumbing added for use as examination and lab rooms; dosing rooms and associated dosing windows will be constructed; a room for the pharmacy and associated medicine vault will be constructed; a check-in booth will be constructed; and electrical, cabling, video, and telephony will be added in/for all rooms. [Supplemental #1, Page 6]

The Applicant reports that the proposed location is 4 Wesley Court, Johnson City, Washington County, Tennessee. The existing building is a free-standing building in what Applicant calls an industrial area, zoned for medical services, approximately 0.2 miles from the Quillen Rehabilitation Hospital. The Applicant acknowledges that Johnson City has "strict zoning requirements regarding locations of [methadone clinics]" [Supplemental #1, Page 10], but also reports that it spent significant time finding a location that best meets the zoning requirements and is well outside all limits that the city has imposed regarding schools, daycare facilities, parks, or locations that sell alcoholic beverages, as shown on a chart supplied with the application. [Supplemental #1, Page 12] It is important to note that the Zoning Code for Johnson City does permit "clinics" within the MS-1 Medical Services District [6.13.2.7], but defines a "clinic" as follows: "A building or portion of a building, other than a hospital, as herein defined, containing facilities providing outpatient medical, dental, chiropractic, optical, osteopathic diagnostic, and similar services, for humans, by physicians, dentists, and other health care specialists. The term clinic includes offices as a separate use for the

above, but does not include Substance Abuse Treatment Facility, or Methadone Treatment Clinic." [City of Johnson City Zoning Code] See Section C.3. for more discussion about zoning.

The proposed location is 1.66 acres and the square footage of the building is 8,260 square feet. Applicant reports that the facility has parking on all four (4) sides of the building, plus on an adjacent side lot and street parking is permitted. Applicant reports that the capacity of parking is sufficient to accommodate patients and, when asked to clarify if the space for the additional parking spaces is already owned by Applicant, the Applicant provided a chart showing the ratio of parking spaces to patients at the proposed facility in comparison to other similar facilities and reported that it is not believed that parking is an issue and no costs were reflected in the Projected Data Chart to remedy a parking problem. [Supplemental #2, Page 5] The proposed site is located on a cul-de-sac with industrial and commercial customers as neighbors. See Section C.3. for discussion on zoning with respect to being located on a cul-de-sac. The Applicant reports that traffic on the street is very light given the limited number [of businesses], hours of operations, and nature of the businesses. [Supplemental #1, Page 10]

The Applicant submitted a line-drawn floor plan showing the location of "counseling" rooms; "storage"; "break room"; "dosing rooms"; "exam room"; "pharmacy" [including vault]; the "check-in/payment" area; the "lobby/reception" area; and a "Group Room". The space marked "pharmacy" raises the question of whether the facility intends to have a pharmacy or if this room has been mis-labeled and is the 'medroom'. If the facility is to have a pharmacy, the Applicant must meet the requirements of the Tennessee Board of Pharmacy. There is also space marked for a "Director", but it is not clear if it is for the Program Director or the Medical Director. [Supplemental #1, Page 15] When asked about seating, Applicant reports that the lobby area could accommodate 153 seats and overflow seating, should it be needed, would be in the common area shown on the diagram.

On the Projected Data Chart [Supplemental #2a, Pages 30 and 31], the Applicant reports gross operating revenue from outpatient services, to an average of 530 patients in the first year of operation (expected to be 2014), of $1,782,144.00. For the second year of operation (expected to be 2015), for services to an average of 1,056 patients, gross operating revenue is reported as $3,903,715.00. Also reported are amounts for charity care of $35,643.00 (Year 1) and $78,074.00 (Year 2). Also reported are amounts for bad debt of $17,821.00 (Year 1) and $39,037.00 (Year 2). The resulting Net Operating Revenue is reported as $1,728,680.00 (Year 1) and $3,786,604.00 (Year 2). The chart shows deductions for operating expenses, other expenses, and capital expenditures of $1,721,042.00 (Year 1) and $3,221,026.00 (Year 2), resulting in a projected Net Operating Income of $7,638.00 (Year 1) and $565,578.00 (Year 2).

As previously stated, when asked to provide data for the Historical Data Chart for Net Operating Revenue, Net Operating Income (Loss), and other such information, for the last three (3) years for a center in Asheville, NC for which Applicant claims ownership, Applicant responded that as a shareholder of the company, not an officer or member of

management, there is no access to this information. [Supplemental #1, Page 34] Without this information, it cannot be determined if the reported projected numbers are in line with data from any of the other seven (7) facilities named in the application.

On Supplemental #1, Page 37, the Applicant reports a proposed charge of $10.00 per day ($70.00 per week) for methadone maintenance treatment at the proposed facility. The Applicant provided a comparison chart [Supplemental #1, Page 38] that shows charges at the proposed facility and those at some of the other facilities named in the application. The Applicant reports that since this is a new project there is no impact to previous charge schedules. The Applicant further reports that the proposed charge is 20%-33% less than charges at the nearest clinics in North Carolina and Tennessee. When asked for a further explanation, Applicant reports "tremendous benefit to lowering the barriers to treatment, and cost is a major factor; Applicant's Manager's other clinics in which he owns a partial interest, [have] tremendous results 'getting the word out' and breaking down barrier to treatment by offering treatment for $1 per day for periods of six months to over a year." [Supplemental #2, Page 7] Elsewhere in the application, it is reported that the Applicant has reviewed and understands the licensure requirements of the TDMHSAS for this type of facility, however, the charge scheme proposed by the Applicant would be prohibited by the TDMHSAS licensure rules.

When asked about participation in Medicare and/or Medicaid, the Applicant responded that the project will not involve the treatment of TennCare participants and that certification will not be sought for Medicare and/or Medicaid. [Applicant Profile, Items 12 and 13, Supplemental #1, Page 3] Further, the Applicant reported that it plans to utilize self-pay programs and does not plan to participate in State and federal programs such as TennCare or Medicare because it "cannot justify the investment of resources required to maintain compliance with TennCare." [Supplemental #1, Page 40] Applicant did note, however, that a call to TennCare Solutions revealed that TennCare patients can be reimbursed for approved medication and services upon individual submission of receipts. When asked for further clarification, Applicant submitted additional information in Supplemental #2 and stated "Applicant will not offer any warranty or representation about TennCare coverage as to any item of service or medication [and] does not intend to make claims on behalf of any patient to TennCare." [Supplemental #2, Pages 2 and 3 of the March 27, 2013 letter] In the March 27, 2013 letter from HSDA to Applicant, it was mentioned that TennCare covers the drug buprenorphine for treatment of opiate addiction and that the medication, medical services, and transportation to providers are covered TennCare benefits. The Applicant was asked to clarify why it is not planning to accept TennCare for suboxone patients. Applicant responded that "the investment in personnel and systems, the on-going compliance and audit requirements, and the risk of penalties for non-compliance do not warrant the added revenue." [Supplemental #2, Page 1 of the March 27, 2013 letter] Further, the Applicant states that based on its experience, there are "additional risks associated with comingling TennCare patients with self-pay patients [such as] arguments, humiliation, etc. such that [it] is not worth implementing TennCare." [Supplemental #2, Page 1 of the March 27, 2013 letter]

When asked about availability of less costly, more effective, and/or more efficient alternative methods of providing the benefits intended by the proposal, the Applicant reported that there is "no treatment in the proposed service area [and that the proposal may appear to be more expensive than the status quo of no service, but] many organizations have documented [that] the cost of untreated persons significantly outweigh the cost of treatment, ..." [Supplemental #1, Page 40] The cited reference is the website of the TDMHSAS, but no particular document, article, or other source of this statement has been provided; therefore, the statement cannot be verified.

As for other alternatives regarding location and/or construction, the Applicant reported that more than fifty (50) locations in the Tri-Cities area were reviewed before selecting the proposed site of 4 Wesley Court. Further, the Applicant reported that the proposed site best meets the zoning requirements and was chosen because it is located in the biggest city of the proposed service area; is close to the maximum number of anticipated patients; has ready highway access to all points within the proposed service area; and requires only modifications to an existing structure, no new construction. [Supplemental #1, Page 41] See Section C.3. for discussion about zoning.

3. Contribution to the Orderly Development of Health Care

As stated elsewhere, the application under review is for a new facility. The Applicant, Tri-Cities Holdings, LLC d/b/a Trex Treatment Center, was organized pursuant to the Georgia Limited Liability Company Act on January 15, 2013 and was established to "engage solely for the formation of an opiate treatment program in the 'Tri-Cities' region of Tennessee and Virginia ...." [Supplemental #1, Page 75] Therefore, the Applicant has no prior experience in the operation of this type of facility or program other than the leadership and experience of its Manager who has "successfully opened nine (9) such facilities in four (4) states in five (5) years." [Supplemental #1, Page 5] When discussing transfer agreements, contractual agreements for health services, and affiliation of the project with health professional schools, since this is a new project, there are no existing agreements and affiliations, but the Applicant reports that it intends to have transfer relationships with all emergency hospitals in the Tri-Cities and surrounding area, including the Johnson City Medical Center and Wellmont Urgent Care (in Johnson City); Holston Valley Medical Center and Indian Path Primary Care (both in Kingsport); Bristol Regional; Union County Memorial (Erwin); Laughlin Memorial (Greeneville); and Hawkins County Memorial (Rogersville). Applicant also reports significant experience developing internships and other partnerships with local universities and professional societies, and looks forward to establishing these with East Tennessee State University's (ETSU's) undergraduate and graduate healthcare programs and Northeast State Community College's Social Work program. [Supplemental #1, Pages 42 and 44] As of the writing of this report, there are no letters of support or opposition from any of these entities; however, the documentation from the 2002 application for a proposed methadone clinic in Johnson City contains a letter of opposition from the then Dean of Medicine and Vice President for Health Affairs at the James H. Quillen College of Medicine at ETSU. The letter indicates that they did not participate in the "development of [the] proposal and do not support the opening of such a clinic in Johnson City." It is not known whether ETSU's position has changed.

When discussing staffing and the availability and accessibility of human resources required for the project, Applicant reports that it recognizes the challenge of hiring and

keeping the right staff and is "experienced and financed ready to meet the challenges." [Supplemental #1, Page 44] Further, Applicant verifies that it has reviewed and understands all licensing certification as required by the State of Tennessee for medical and clinical staff. When asked to clarify if a Program Director or Medical Director has been identified and to provide their names and background, Applicant responded that candidates have been interviewed and meet certification requirements, but due to the "uncertainty with respect to approval and timing, offers cannot be extended and candidates do not wish to be identified." [Supplemental #1, Page 43] When asked to clarify whether the Substance Abuse Counselors will be certified, the Applicant reports that all personnel will satisfy the State Minimum Program Requirements for Non-Residential Opioid Treatment Program Facilities, Staff Qualifications [Personnel and Staffing Requirements], Rule 0940-05-42-.29 [Supplemental #1, Page 43], however, the staffing chart provided on Supplemental #1, Page 43 does not contain enough information to determine, at this time, if the staffing requirements will be met and if staff will have the appropriate certifications. For instance, there is no mention of Physician Assistants or Advance Practice Nurses, no mention of a Program Physician, and no mention of which personnel will serve as Community Relations Coordinators. Applicant reports that a Security Guard is not planned, but if the need arises, a Security Guard will be hired. [Supplemental #1, Page 43]

For the criteria requesting documentation of deficiencies, if any, for existing licensed providers, the response is "not applicable". [Supplemental #1, Page 45] When requested to provide health survey results for the centers in North Carolina for which the Applicant's Manager claims "co-founder" and "part-owner" status, the response was that Applicant is a "shareholder of the company that operates these centers, but is not an officer or member of management ... [so] has no access to these records." [Supplemental #1, Page 45]

When discussing the understanding of standards and requirements, Applicant verifies that it has reviewed and understands the licensure requirements of the Department of Health, the Department of Mental Health and Substance Abuse Services, and/or any applicable Medicare requirements. In information provided in Supplemental #2 [Page 4 of a Mach 27, 2013 letter], Applicant also reports that TDMHSAS staff explained the licensing and Central Registry procedures for this type of program, however, the response to whether the Applicant will provide the HSDA and/or the reviewing agency information concerning the number of patients treated, the number and type of procedures performed, and other data as required, the Applicant responded "Yes, subject to Federal HIPAA regulation." [Supplemental #1, Page 45] It is unclear whether Applicant is fully aware of and understands the complexity of all federal, Tennessee, and local laws, regulations, rules, and ordinances governing the establishment and operation of this type of facility and program. It should be noted that the requirement to provide data for a Methadone Central Registry is a federal regulation and is also required by the TDMHSAS licensure rules, but has nothing to do with the HIPAA regulations.

When asked about alternatives, the Applicant reported that more than fifty (50) locations in the Tri-Cities area were reviewed before selecting the proposed site of 4 Wesley Court. Further, the Applicant reported that the proposed site best meets the zoning requirements and was chosen because it is located in the biggest city of the

proposed service area; is close to the maximum number of anticipated patients; has ready highway access to all points within the proposed service area; and requires only modifications to an existing structure, no new construction. [Supplemental #1, Page 41] The Applicant reports that it has "balanced cost control with providing patients quality care and a healing environment." [Supplemental #1, Page 41] As mentioned elsewhere, the proposed site is located on a cul-de-sac with industrial and commercial customers as neighbors. See Section C.3. for discussion on zoning with respect to being located on a cul-de-sac. The Applicant reports that traffic on the street is very light given the limited number [of businesses], hours of operations, and nature of the businesses. [Supplemental #1, Page 10] The Applicant was asked to provide, if possible, letters of support from the businesses that are located in the immediate area of the proposed location. Information provided in Supplemental #2 indicates that the other two (2) businesses located on Wesley Court are related to construction and the Applicant contacted the landlord/owner of one of the businesses and the individual "voiced no opposition" and the landlord of the Applicant's proposed site "knows the owner/landlord of the other business and has briefed that individual, and this individual has voice[d] no opposition to date. The Applicant would characterize their responses as neutral." [Supplemental #2, Page 4 of the March 27, 2013 letter]

As for the zoning requirements, in the March 15, 2013 letter from HSDA to Applicant, the Applicant was requested to provide a current letter from the City of Johnson City that the proposed site meets zoning requirements. Staff of the TDMHSAS reviewing the application cannot find the requested documentation, but do take note of statements in the application that the Applicant has requested zoning variances to accommodate this project. In Supplemental information, as requested, the Applicant provided a copy of the City of Johnson City zoning requirements [Supplemental #1, Pages 106-109]. As these zoning requirements show, the Board of Zoning Appeals is permitted to approve such a facility as a "special exception" only if the proposed facility complies with all five (5) criteria contained in Section 6.13.3.4 A.-F. As noted in other supplemental information, the proposed site for the facility is on a cul-de-sac, not an arterial street; therefore, does not comply with required criteria. Further, the proposed hours of operation are other than that required in the criteria. In Supplemental #2 information, the Applicant, when asked how it intends to address the zoning regulations, particularly the cul-de-sac versus arterial street and the proposed hours of operation, the response is that Applicant has requested a zoning variance from Johnson City. [Supplemental #2, Page 4] It should be noted that the Board of Zoning Appeals has no authority to grant a variance to special exceptions set forth in a Zoning Code, their role is to ascertain whether all criteria of a special exception have been met or not.

sbg
:sbg